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14. ABSTRACT The U.S. military is providing amputees with state-of-the-art prosthetic devices that allow them to more easily adapt to the different surfaces and environments they are faced with in the community. In addition to walking and changing direction, amputees must be able to manage uneven terrain, crowded environments, stairs, ramps, and hills. ***The largest problem for a lower extremity amputee is falls***. Even with the newer technologies, falls and injuries due to falling are still an issue. Falling history and balance confidence are associated with reduced mobility capability and social activity. ***The goal of this research effort is to rehabilitate* individuals with lower extremity *amputations to reduce falls using a novel training method.*** The training program utilizes a microprocessor-controlled treadmill designed to deliver task-specific training perturbations. The training consists of six, 30 minute sessions delivered over a 2-week period. Trunk motion and velocity were assessed using a perturbation test in an immersive virtual environment, since trunk kinematics has been shown to determine fall likelihood. We have enrolled 18 research subjects at the Naval Medical Center San Diego. Mean trunk flexion angle and velocity significantly improved after participating in the training program. The improved performance was maintained up to 6 months. Subjects reported decreased uncontrolled and semi-controlled falls in their free-living environment outside of the research laboratory. ***These results indicate that task-specific training is an effective rehabilitation method to reduce falls in persons with lower limb amputations.***

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Abstract

The U.S. military is providing amputees with state-of-the-art prosthetic devices that allow them to more easily adapt to the different surfaces and environments they are faced with in the community. In addition to walking and changing direction, amputees must be able to manage uneven terrain, crowded environments, stairs, ramps, and hills. ***The largest problem for a lower extremity amputee is falls***. Even with the newer technologies, falls and injuries due to falling are still an issue. Falling history and balance confidence are associated with reduced mobility capability and social activity. ***The goal of this research effort is to rehabilitate* individuals with lower extremity *amputations to reduce falls using a novel training method.*** The training program utilizes a microprocessor-controlled treadmill designed to deliver task-specific training perturbations. The training consists of six, 30 minute sessions delivered over a 2-week period. Trunk motion and velocity were assessed using a perturbation test in an immersive virtual environment, since trunk kinematics has been shown to determine fall likelihood. We have enrolled 18 research subjects at the Naval Medical Center San Diego. Mean trunk flexion angle and velocity significantly improved after participating in the training program. The improved performance was maintained up to 6 months. Subjects reported decreased uncontrolled and semi-controlled falls in their free-living environment outside of the research laboratory. ***These results indicate that task-specific training is an effective rehabilitation method to reduce falls in persons with lower limb amputations.***

Introduction

The US global war on terrorism has resulted in many US warfighters sustaining extremity injuries. The US military is currently fitting amputees with state-of-the-art prosthetic devices. While amputees may try to focus on the advanced technology to try to solve some of the adjustment issues, "high tech" does not always equate to "high function". In addition to walking and changing direction on a variety of surfaces, amputees must be able to manage uneven terrain, crowded environments, stairs, ramps, and hills. The key factor that limits the ability of amputees to achieve maximum functional capabilities is falls. Among individuals with a lower extremity amputation, 52% reported having fallen in the last 12 months, 49% reported being fearful of falling, and 65% have low balance confidence scores. Falls in warfighters with a lower extremity amputation can have serious consequences, including loss of confidence, fear of falling, and injury. As a result, those individuals with limited balance and stability are at risk for diminished quality of life. The goal of this research effort is to rehabilitate warfighters with a lower extremity amputation to increase trust in their prosthesis and reduce falls by using a novel training method. Deliverables include a quantitatively derived, deployment ready, advanced gait rehabilitation system and method that can improve functional outcome and/or shorten the time required for injured service men and women to return to active duty or to a productive civilian life.

Body

This was the third year of a research effort to develop and test a novel training technique aimed at increasing and/or accelerating the functional capabilities of warfighters with a lower extremity amputation and enhancing their return to active duty or a productive civilian life. Our efforts have focused on enrollment and training.

18 subjects (15 transtibial and 3 transfemoral) have been enrolled (Figure 1). The protocol calls for subject functional capabilities to be collected at four time points. Subjects are tested before starting the training protocol to establish their baseline capabilities. The subsequent training consists of 6 training sessions over a 2-week timeframe. The subjects are tested again following completion of the training. To evaluate the extent to which the training is maintained, all subjects are assessed for functional outcomes at 3 and 6 month time points following completion of the training. 14 subjects have completed the training, and 11 have completed the 3 and 6 month follow-up evaluations.

We have experienced compliance issues with this project. Three subjects completed the training but not the final 6-month post training assessment: Two of these subjects moved out of the San Diego area before we could capture the 6-month assessment, and one subject was competing in a bike race, fell and fractured his pelvis. Three subjects dropped out during the training portion of the study: One subject required residual limb surgical revision; one subject had psychological issues requiring hospitalization, and one subject dropped out due to the time commitment. Importantly, none of the dropouts were due to the training program. One subject has been delayed for his 6-month assessment due to prosthetic issues, but we are planning on him to complete the study.

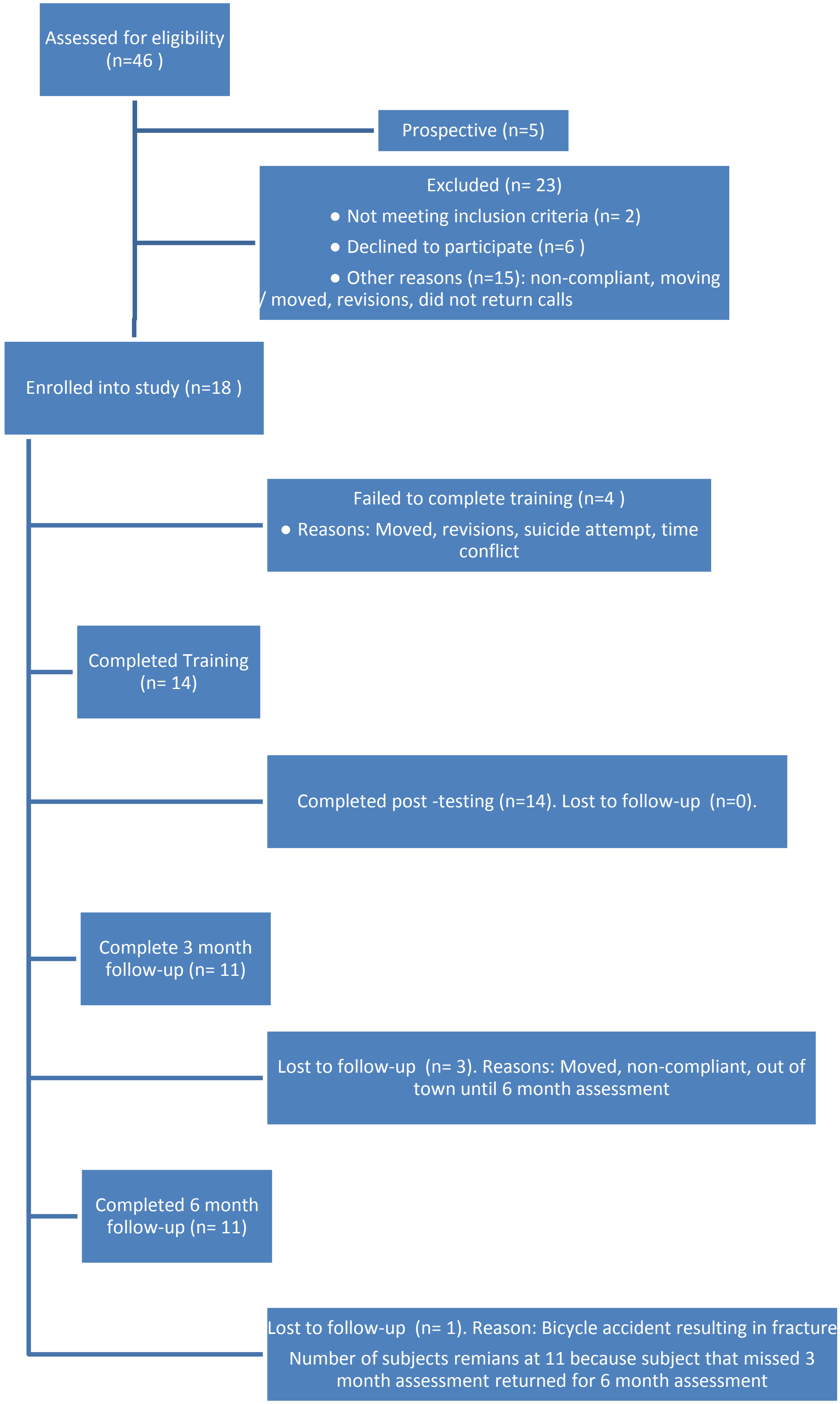


Figure 1. Subject flow through study.

Active recruitment for the project is ongoing. Contacts have been established with the local VA for identification of subjects. In addition, the IRB protocol has been modified and approved to reach out to subjects residing in the San Diego catchment area who were rehabilitated at Walter Reed/Bethesda or the Center for the Intrepid. Further, we have located a database at the Naval Health Research Center-San Diego which provides us with contact information of individuals in the San Diego area who might be able to participate in the study. We have recently obtained IRB approval to contact these individuals. We also received feedback that a monetary incentive would help with our recruitment and the guidelines on monetary incentives have changed in this past year. We recently received IRB approval to provide monetary incentives to our subjects when they complete the training and post-training assessment, the 3-month assessment and the 6-month assessment. We are hoping this will help with our recruitment efforts while appropriately reimbursing the subjects for their time, effort and costs associated with participation.

The fall prevention training program utilizes an Active-Step treadmill (Simbex, Lebanon, NH). This microprocessor-controlled treadmill is designed to deliver task specific training perturbations. Three types of perturbations are used during six, 30 minute training sessions conducted over a 2-week period. During each training session, the task difficulty is increased as the patient's ability progresses. Three types of perturbations are delivered to subjects at each training session. Two "static" and one "dynamic" perturbations are used: (1) *static step*: the belt is moved while the patient is standing still and the patient responds with one forward step; 2) *static walk*: the belt is moved while the patient is standing still and the patient must respond with multiple forward steps: and 3) *eTRIP*: while the subject is walking on the treadmill the perturbation is delivered at a random time and the subject must respond with multiple forward steps.

Assessment of the training program effectiveness is done using a perturbation testing protocol in a Computer Assisted Rehabilitation Environment (CAREN, Motek Medical BV, Amsterdam). This fully immersive virtual environment contains a 6 degree-of-freedom motion platform containing an instrumented dual belt treadmill with integrated force plates. The platform is surrounded by a 180 degree screen. During the testing protocol perturbations simulating a trip in the natural environment are delivered. Six perturbations (3 left limb/3 right limb) are delivered in a randomized manner while the subject walks for five to six minutes at a velocity standardized to leg length. This test assessment of the rehabilitative program is performed before and after the two week training on the Activestep treadmill. The key outcome variables are peak trunk flexion and trunk velocity between time of treadmill perturbation and recovery step completion. These variables have been shown to determine the likelihood of a fall.

Patient centered information is also collected prior to and at the conclusion of the training using two questionnaires. The Prosthesis Evaluation Questionnaire (PEQ-A) is used to quantify patient satisfaction. For the PEQ-A, an uncontrolled fall is defined as a sudden loss of balance without any time to protect against a fall. A semi-controlled fall is defined as a loss of balance with awareness that a fall is occurring so that there is the opportunity to brace for the fall or catch something in order to not get hurt and land in a protected fashion. The Activity-Specific Balance Confidence Scale (ABC) is used to assess the subject's perceived balance confidence.

The research program had 4 tasks. The results will be presented for each task.

Task 1: *Conduct installation and training at the Naval Medical Center, San Diego*

COMPLETED

Task 2: *Assess functional performance improvements in amputees using the treadmill training system*

<u>Lab Assessments</u>: The training program has been beneficial. All study subjects were considered high functioning based on their baseline ABC questionnaire scores (90 ± 8, 95% CI: 86 to 95). There were

no changes in ABC score over time (p=0.86). At 6 months, the ABC score was 92 ± 9 (95% CI: 84 to 99). Nonetheless, the training program resulted in improvements of the perturbation-induced peak trunk flexion angle and trunk flexion velocity for both prosthetic and non-prosthetic limbs (Figure 2). The prosthetic limb trunk flexion angle improved from pre-training (42 degrees; 95% CI, 38-47) to after training (31 degrees; 95% CI, 25-37; p<0.001). Likewise, the trunk flexion velocity improved from pre-training (187 degrees/sec; 95% CI, 166-209) to after training 143 deg/sec; 95% CI, 119-167; p<0.004). The results display a significant side-to-side difference for peak trunk flexion angle (p=0.01), with perturbations of the prosthetic limb resulting in higher peak angles. Prosthetic limb trips also exhibited significantly greater peak trunk flexion velocity compared with trips of the prosthetic limb (p=0.005).

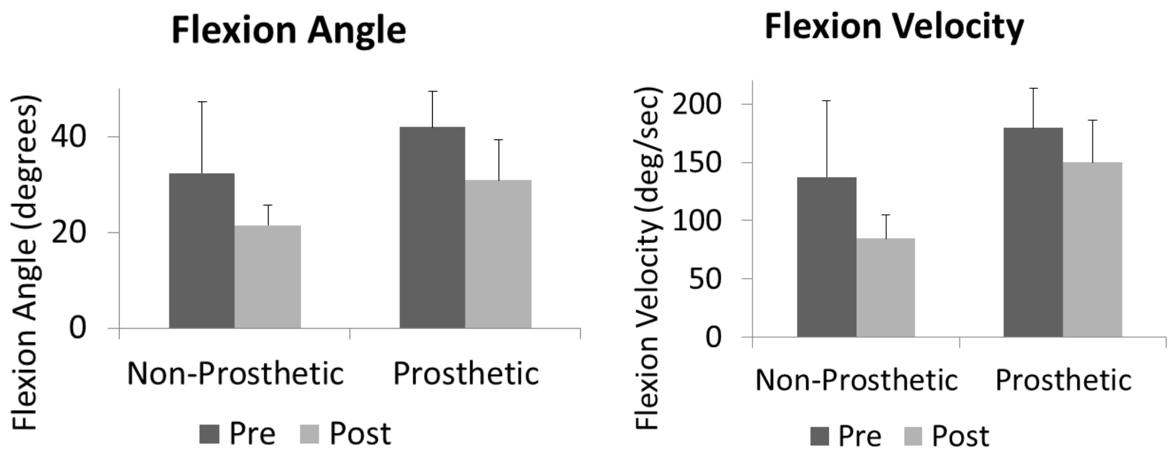


Figure 2: Trunk flexion angle (degrees) and velocity (deg/sec) before and after training when the subjects were subjected to gait perturbations of the prosthetic and non-prosthetic limb. There were statistically significant changes in trunk kinematics angle. Perturbations of the prosthetic limb resulted in significantly greater changes. The data demonstrated a clinically significant improvement in ability to recover from a postural perturbation and avoid falling.

Standard Perturbation Test: Before beginning the training program, a standard perturbation was administered without telling the subject which leg to use to avoid falling. Subject was considered to pass the standard perturbation if he recovered without assistance from the harness and considered to have failed if they fell and the harness had to catch them. Looking at the subjects with a transtibial amputation, in this pretest condition 10 of 11 subjects (91%) failed and 5 of the 10 subjects (50%) who fell elected to attempt recovery on the prosthetic limb. Following training, the standard perturbation was administered again. After the two week training, all subjects passed the standard perturbation and 7 of the 11 subjects (64%) chose to use the *prosthetic* limb as their recovery step to avoid falling. These results demonstrate increased reliance on the prosthetic limb.

Fractal Analysis of Foot Placement During Treadmill Locomotion: During locomotion, control of frontal plane stability is not a trivial biomechanical task. Placement of the foot on the ground at the conclusion of swing phase establishes step width. Step width, the frontal plane distance between the feet during the double stance phase, is the most important variable affecting frontal plane dynamic stability during gait. We have applied fractal analysis of step width time series data to determine the presence of time-dependent structure in the data. Randomness in the step width time series data, reflecting lower time-dependent structure, is reflective of diminished nervous system control. Ten consecutive minutes of step width data from 14 rapid rehabilitation subjects walking on the CAREN system was subjected to fractal analysis. The resulting fractal coefficient had a mean of -0.49±0.15 (95% confidence interval: -0.40 - -0.58). The mean was 37% lower than that of a small control group of non-amputees (-0.67±0.15). These preliminary results, which point to a higher degree of randomness in the step width time series of the rapid rehabilitation subjects, suggest a potentially clinically important difference in nervous system control. Notably, the increased randomness and its potential implications are not evident in the traditionally used mean value of step width or coefficient of variation. The step width of the amputee subjects (147±51 mm) was 13% larger than that of the control group (128±36 mm). The coefficient of variation of the rapid rehabilitation subjects (35%) was seven percent larger than that of the control group (28%).

Task 3: *Evaluate the ability of the treadmill system to achieve rapid rehabilitation of amputees*

Comparison with amputee control group: Comparisons were also made between patients who had not been enrolled in the research study to patients who had participated in the training. These amputee control subjects were selected from patients who had previously been studied in the Gait Laboratory at the Naval Medical Center-San Diego. Patients were matched based on age, BMI, residual limb length and amount of time they had been walking without an assistive device. There were no significant patient demographic differences between the subjects enrolled in the study and this amputee control group. Both groups were studied at three time points which were spaced 3 months apart. The only difference is that the amputee control group did not receive the novel fall-prevention training.

Stride length variability was used as a measure of balance control. There was no significant difference in the two groups at the baseline (Month 0) testing (p=0.5). Importantly, there were significant differences in gait characteristics between the trained group and the amputee control group at the follow-up time points (p=0.045). The trained subjects demonstrated a decrease in their stride length variability which indicates improved control (Figure 3).

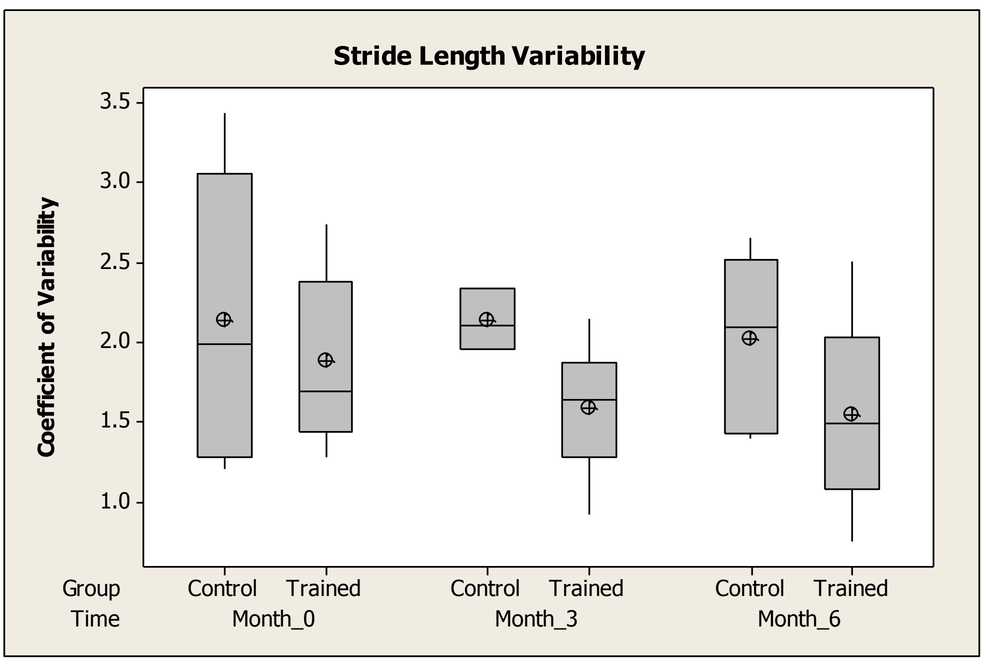
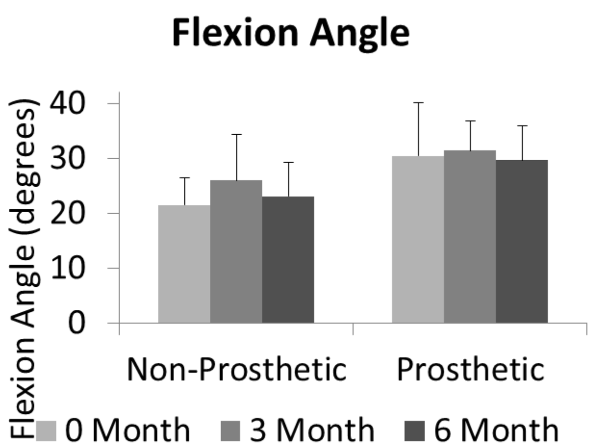


Figure 3. Changes in the stride length coefficient-of-variability over a 6 month period for the amputee control group and the group receiving the novel rehabilitation (trained group). The central line represents the median, the edges of the box are the 25th and 75th percentiles, the whiskers extend to lowest and highest datum within 1.5 x the interquartile range, and the filled circle is the mean. A lower value (lower variability) indicates an improvement. The trained group had clinically meaningful improvements in their stride characteristics.

Task 4: *Evaluate motor skill retention following completion of rehabilitation training*

<u>Lab assessments:</u> Importantly, the skills acquired were retained at 3 and 6 months after training (Figure 4). The trunk flexion angle of the subjects when the prosthetic limb was perturbed had a mean of 31 degs (95% CI, 25-37) at 0 month, 32 degs (95% CI, 28-37) at 3 months, and 30 degrees (95% CI, 25-34) at 6 months. Likewise, the trunk flexion velocity for the prosthetic limb was a mean of 143 degs/sec (95% CI, 118-167) at 0 months, 143 degs/sec (95% CI, 126-159) at 3 months, and 132 (95% CI, 115-149) at six months. The peak trunk flexion angle when the non-prosthetic limb was perturbed had a mean of 22 degs (95% CI, 18-24) at 0 months, a mean of 26 degrees (95% CI, 20-32) at 3 months, and a mean of 23 degrees (95% CI, 19-28) at 6 months. The peak trunk flexion velocity for the non-prosthetic limb had a mean of 85 degs/sec (95% CI, 71-98) at 0 months, a mean of 96 (95% CI, 68-124) at 3 months, and 87 degs/sec (95% CI, 68-105) at 6 months. There were no significant changes in the peak trunk flexion angle (p = 0.16) or peak trunk flexion velocity (p = 0.35) over time after the training ended. The skill retention was present when either the prosthetic or non-prosthetic limb was perturbed. There were side-to-side differences in the trunk flexion angle (p = 0.038) and trunk flexion velocity (p=0.004). Perturbations of the prosthetic side resulted in larger trunk flexion and higher trunk flexion velocities.



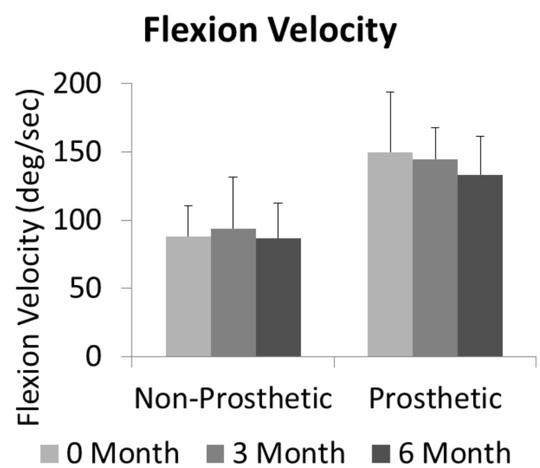


Figure 4: Trunk flexion angle (degrees) and velocity (deg/sec) over time following completion of the training. There were no significant changes in trunk kinematics. Perturbations delivered to the prosthetic side resulted in significantly higher trunk flexion angles and velocities than when these same disturbances were delivered to the non-prosthetic side. The data demonstrates that the subjects are able to retain the training effect up to six months after completing the training.

<u>Questionnaire evaluations:</u> Patient-reported outcomes confirmed the success of the training program. Their responses indicated increased confidence in their ability to recover from the postural perturbations in the community. Sixty percent of the subjects reported that the incidence of stumbles had decreased after the training program. Most of the subjects (80%) indicated that the number of semi-controlled falls had been reduced to zero after training. All subjects (100%) reported that the number of uncontrolled falls was zero after training. Reduction of stumbles and falls was maintained over time.

Key Research Accomplishments

- 14 subjects enrolled and trained
- Training is accomplished in six, 30 minute sessions conducted over a 2 week period
- Data demonstrates improvements in ability of transtibial amputees to avoid a fall following large postural perturbations
- Military personnel undergoing the novel rehabilitation training are showing greater improvements in their gait over a shorter time-frame compared to an amputee control group.
- Critical training effects are retained for at least 6 months following completion of the training
- Amputees report reduction in falls in their free-living environment
- We have data on three subjects with transfemoral amputations before and after training. Analysis of their data is in process.

Reportable Outcomes

- Abstracts on the research program have been presented at
    - International Society of Biomechanics, Natal, Brazil, August 4-9, 2013
    - Military Health System Research Symposium, Fort Lauderdale, FL, August 12-15, 2013
    - American Society of Biomechanics Meeting, Omaha, NE, September 4-7, 2013

- Papers
    - One paper published
      Sessoms PH, Wyatt M, Grabiner M, Collins JD, Kingsbury T, Thesing N, Kaufman K. Method for evoking a trip-like response using a treadmill-based perturbation during locomotion. *Journal of Biomechanics*, 47(1):277-280, 2014.

    - Another paper in revision
      Kaufman KR, Wyatt MP, Sessoms PH, Grabiner MD. "Task specific Fall Prevention Training is Effective for Warfighters with Transtibial Amputations", *Clinical Orthopedics and Related Research.*

Conclusion

We have designed and developed a demonstrably effective, clinically relevant and scientifically based method for increasing and accelerating the progressive adaptation of warfighters with a lower extremity amputation to their prosthesis. This rehabilitation method uses a novel and innovative treadmill training method. The training method is aimed at increasing the ability for amputees to rely on their prostheses, particularly in a challenging environment, and thus, improve their functional capabilities. Based on the results obtained to date, warfighters with unilateral amputations have reduced falls and retained their improved skills for at least six months following training.

In order to test the outcomes in a repeatable and reliable manner, we have also developed a test protocol on the CAREN which allows us to cause postural perturbations which result in falls in untrained individuals. This protocol will have utility in assessing other interventions aimed at improving the gait and stability of warfighters with lower extremity amputations.

Future work should expand this research program to warfighters with bilateral lower extremity amputations and service members with limb salvage procedures. The current program is only enrolling subjects with unilateral amputations. This enrollment criterion was used to validate the method on individuals who are not as mobility challenged. Further, when the program was conceived, there was not the preponderance of bilateral lower extremity amputees. Given the success of the current program, advancing the training to other warfighters is now warranted.